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HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,006	LOVETT ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86--98,100-108,110-117 and 120-123* is/are pending in the application.

4a) Of the above claim(s) *90,100,108,110 and 120* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-89,91-98,101-107,111-117 and 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species 1B in the reply filed on 2/10/2009 is acknowledged. Applicant's election with traverse of Species 2A in the reply filed on 2/10/2009 is acknowledged. The traversal is on the ground(s) that there is a discrepancy between the description of Species 2 and the language in the claims. It is acknowledged that Applicant's interpretation of the Restriction Requirement is correct. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 90, 100, 108, 110, and 120 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

3. **Claims 86-89, 91-98, 101-107, 111-117, and 121-123** remain pending and prosecution.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-2, 4-10, 14-21, 23-26, 31, and 41-48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Varieur et al (US Pub No. 20050149053) in view of Ferree (US Pub No. 20040225228).

6. In regards to **Claim 1**, Varieur et al disclose a system for use during a spinal surgical procedure in a patient, comprising:

an anchor 100 engageable to a vertebral body, best seen in Figure 16-17;

an extender 12 including an elongated body extending between a distal end 22A, B removably mountable to said anchor and a proximal end 20A, B, said body defining a passage that extends between and opens at said distal and proximal ends of said body, best seen in Figure 4.

7. However, Varieur et al do not explicitly disclose said extender comprised of an electrically conductive material and further including an insulating member. Varieur et al do disclose that said extender may be made of metal (¶0032). Ferree teach a system for monitoring nerve proximity during a spinal surgical procedure in a patient comprising providing electricity to stimulate screwdriver 902 and thus pedicle screw 904 while insulating sleeve 906 extends proximally from a distal end about at least a portion of a body and prevents shunting of electricity into the tissues surrounding the spine, best seen in Figure 9, as an effective device to determine if the pedicle screw is properly positioned away from spinal nerves (¶0005, 0010).

8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the extender of Varieur et al to be comprised of an electrically conductive material and further including an insulating member extending proximally from said distal end about at least a portion of said body of said extender, said insulating member being comprised of a material having properties to insulate structures adjacent said portion of said body from an electrical signal delivered through said body of said extender to said anchor when said

extender is mounted to said anchor in the patient, as taught by Ferree et al, to effectively monitor nerve proximity to the anchor after it's insertion during the spinal surgical procedure.

9. In regards to **Claim 2**, Varieur et al disclose said passage is sized for receipt of a surgical instrument 14, 70 engageable to said anchor 100 to engage said anchor to the vertebra, best seen in Figure 16-17.

10. In regards to **Claim 4 and 23**, Varieur et al disclose said passage is open along at least a portion of a length of said body, best seen in Figure 4.

11. In regards to **Claim 5**, Varieur et al disclose said anchor 100 includes a lower portion for engaging the vertebral body and a receiver 102, 104 for engagement with an implant 110 positionable along the vertebral body when the lower part of the anchor is engaged to the vertebral body, best seen in Figure 16-17.

12. In regards to **Claim 6**, Varieur et al disclose the implant 110 is selected from a group consisting of: a rod and a plate, best seen in Figure 17.

13. In regards to **Claim 7 and 24**, Varieur et al disclose said receiver 102, 104 includes a proximally extending portion comprising a mounting portion for receiving the implant 110 and said extender 12 is removably mounted with said mounting portion, best seen in Figure 17.

14. In regards to **Claim 8 and 25**, Varieur et al disclose said receiver 102, 104 is pivotal relative to said lower portion, best seen in Figure 17.

15. In regards to **Claim 9 and 26**, Varieur et al disclose said receiver 102, 104 and said lower portion 100 are uni-axial, best seen in Figure 17.

16. In regards to **Claim 10**, Varieur et al disclose said receiver 102, 104 includes a U-shaped passage for receiving a rod 110, best seen in Figure 17.

17. In regards to **Claim 14**, Varieur et al in combination with Ferree et al disclose the invention above but do not explicitly disclose said insulating member includes at least a first component and a second component. Ferree et al teach another analogous insulating member 1108 including a first component and a second component removably coupled to said first component, best seen in Figure 11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the insulating member of Varieur et al as modified by Ferree et al comprised of a first and second component and said components extending substantially about said body of said extender when coupled to one another as an effective structure to insulate the adjacent tissue from the electrical signal to test for nerve proximity to the anchor.

18. In regards to **Claim 15**, Ferree et al disclose said first and second components are longitudinally coupled to one another, best seen in Figure 11.

19. In regards to **Claim 16**, Varieur et al in combination with Ferree et al disclose the invention above but do not disclose said first and second components of the insulating member includes pins and receptacles therealong to couple said first and second components to one another about said body of said extender. Varieur et al teach that first and second components 18A-B include a number of pins 35, and receptacles 46 therealong, said pins being removably received in corresponding ones of said receptacles to couple said first and second components to one another about said body of said extender, best seen in Figure 4 and 9-10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first and second components of the insulating member of Varieur et al as modified by Ferree et al with pins and receptacles to effectively couple the first and second components to one another about said body of said extender.

20. In regards to **Claim 17**, Varieur et al in combination with Ferree et al disclose said first and second components extend completely about said body portion when coupled thereto.

21. In regards to **Claim 18**, Varieur et al disclose said extender 12 includes a pair of arms at a distal end 22A,B thereof, said arms being movable toward one another to mount said anchor 100 therebetween and movable away from one another to release said anchor, best seen in Figure 16-17. Ferree et al disclose said first and second components each including outwardly extending feet adapted to extend along respective ones of said arms, best seen in Figure 11 B, C.

22. In regards to **Claim 19 and 41-42**, Varieur et al in combination with Ferree et al disclose said extender 12 includes a proximal end portion extending proximally of said insulating member, best seen in Figure 9 of Ferree et al.

23. In regards to **Claim 20 and 31**, Varieur et al disclose said extender 12 above but do not teach the extender includes an electrical lead extending from said proximal end portion. Ferree et al teach an electrical lead 1660 extending from a proximal end portion of an analogous extender, best seen in Figure 16A. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the extender of Varieur et al as modified by Ferree et al to have an electrical lead extending from said proximal end portion to effectively couple the extender to the electrical source for stimulation.

24. In regards to **Claim 21 and 46**, Varieur et al disclose a system for use during a spinal surgical procedure in a patient, comprising:

an anchor 100 engageable to a vertebral body with a lower portion engage able to a vertebra, best seen in Figure 16-17;

an extender 12 including an elongated body extending between a distal end 22A, B and a proximal end 20A, B, said body defining a passage from said proximal end to said distal end, wherein said body of said extender includes a C-shaped cross section at least along at least a part of its length, said C-shaped body including a convexly curved outer surface capable of retracting tissue and an opposite concavely curved inner surface defining said passage, best seen in Figure 4-6.

25. However, Varieur et al do not explicitly disclose said body of the extender providing an electrically conductive pathway and further comprising an insulating member. Varieur et al do disclose that said extender may be made of metal (¶0032). Ferree teach a system for monitoring nerve proximity during a spinal surgical procedure in a patient comprising providing electricity to stimulate screwdriver 902 and thus pedicle screw 904 while insulating sleeve 906 extends proximally from a distal end about at least a portion of a body and prevents shunting of electricity into the tissues surrounding the spine, best seen in Figure 9, as an effective device to determine if the pedicle screw is properly positioned away from spinal nerves (¶0005, 0010).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the extender of Varieur et al to be comprised of an electrically conductive material to define an electrically conductive pathway to said anchor when said anchor is removably mounted thereto, and further comprising an insulating member extending about at least a portion of said body of said extender to insulate structures adjacent said portion of said body from an electrical signal delivered through said body of said extender to said anchor when said extender is mounted to said anchor, as taught by Ferree et al, to effectively monitor nerve proximity to the anchor after it's insertion during the spinal surgical procedure, wherein it would also be obvious to have the insulating member include a C-shaped cross section, similarly shaped with the C-shaped cross section of said extender above, wherein the insulating member extends longitudinally along said body of said extender about at least said convexly curved outer surface of said body of said extender for the reasons elaborated above.

27. In regard to **Claims 43 and 47**, Varieur et al disclose said body of said extender 12 includes first and second securing members 92A, B, 93 extending therethrough for mounting said extender to said receiver 102, 104 of said anchor 100, best seen in Figure 16 A, B.

28. In regards to **Claims 44 and 48**, Varieur et al disclose said securing members are elongated pins 93 that are rotatable relative to said body of said extender 12 to threadingly engage said receiver 102, 104.

29. In regards to **Claim 45**, Varieur et al in combination with Ferree et al disclose said insulating member is removably engaged to said body of said extender 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736